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| 10/721,476 | 11/25/2003 | James A. Joy | 221901-1010 | 6021 |

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| EXAMINER | |
|---|---|
| TOTH, KAREN E | |
| **ART UNIT** | **PAPER NUMBER** |
| 3735 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/02/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/721,476 | JOY ET AL. | |
| | Examiner | Art Unit | |
| | Karen E. Toth | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *34-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892).
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of claims 1-33 in the reply filed on 21 December 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 34-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 21 December 2006.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5-7, 12, 21, 22, 24-28, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Karakasoglu (US Patent 6213955).

Regarding claims 1 and 2, Karakasoglu discloses a portable data acquisition unit comprising a solid-state pressure sensor configured to measure pressure signals related to patient breathing (elements 71, 71a; column 3, lines 35-45); a microcontroller (element 101) that receives the pressure signals and determines their associated clock

times (column 4, lines 24-56); and an interface that is configured to output data from the unit to another device (column 10, lines 24-26). The examiner notes that Karakasoglu does not explicitly disclose measuring the pressure signals at a high-frequency rate; however, the current application does not provide a limiting definition of the term "high-frequency", and sampling at any rate may thus be considered a high frequency rate. This will be considered to apply to all further uses of "high-frequency" in the present claims.

Regarding claim 5, Karakasoglu further discloses using the system to measure data at a rate of 6-10 kHz (column 6, line 59).

Regarding claim 6, Karakasoglu further discloses that the microprocessor is a digital signal processor (column 4, line 45).

Regarding claim 7, Karakasoglu further discloses that the microprocessor comprises non-volatile memory (column 9, lines 50-55).

Regarding claims 8 and 9, Karakasoglu further discloses that the memory comprises logic configured to generate sleep session data by using the pressure and time data to identify sleep disordered breathing events (column 8, lines 40-55; column 10, lines 1-10)

Regarding claim 12, Karakasoglu further discloses the system comprising an amplifier that amplifies the pressure signals and an analog-to-digital (A/D) converter that converts the amplified pressure signals into digital signals for the microcontroller (figure 5; column 6, lines 15-24).

Regarding claim 21, Karakasoglu discloses a data acquisition program stored on a computer-readable medium comprising logic configured to receive measured pressure signals and store the signals as pressure data (step 131 of figure 5); logic configured to determine times at which the measured signals were measured and store the data as time data (column 4, lines 52-56); and logic configured to transmit the data to a computer (column 10, lines 24-26).

Regarding claim 22, Karakasoglu further discloses logic configured to reduce the amount of stored data (column 7, lines 5-58).

Regarding claim 24, Karakasoglu further discloses logic configured to identify sleep disordered breathing events through analysis of the pressure and time data (column 8, lines 40-55; column 10, lines 1-10).

Regarding claim 25, Karakasoglu further discloses storing the program on the medium of a portable data acquisition device (column 9, lines 50-55).

Regarding claim 26, Karakasoglu discloses a method of collecting sleep session data from a patient comprising providing to a patient a portable data acquisition unit that is configured to collect pressure data (column 3, lines 35-45; figure 1); measuring pressure signals as the patient sleeps (column 4, lines 65-67) and recording a time at which each pressure signal is collected (column 4, lines 52-56); downloading pressure and time data from the unit to a computer, and manipulating the downloaded data with the computer (column 10, lines 24-27).

Regarding claim 27, Karakasoglu further discloses that the unit is configured for wearing by the patient during sleep (column 2, lines 21-26).

Regarding claim 28, Karakasoglu further discloses measuring data at a rate of 6-10 kHz (column 6, line 59).

Regarding claims 31 and 32, Karakasoglu further discloses analyzing the data to identify sleep disordered breathing events (column 8, lines 40-55; column 10, lines 1-10, 24-26) before the data is downloaded to a computer.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunning (US Patent 4296756).

Regarding claims 1 and 2, Dunning discloses a portable data acquisition unit comprising a solid-state pressure sensor configured to measure pressure signals related to patient breathing (elements 10, 42); a microcontroller (column 6, lines 12-16) that receives the pressure signals and determines their associated clock times (column 5, lines 49-51); and an interface that is configured to output data from the unit to another device (element 38).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 3, 4, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Westbrook (US Patent Application Publication 2002/0165462).

Regarding claim 3, Karakasoglu discloses all the elements of the current invention, as described above, except for the pressure sensor being a strain gauge. Westbrook teaches a system for sensing sleep data using a pressure sensor that may be a strain gauge (paragraph [0089]), since it is well-known in the art to use strain gauges to measure pressure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu with a strain gauge to measure pressure, as taught by Westbrook, since it is well-known in the art to use strain gauges to measure pressure.

Regarding claim 4, the examiner notes that Westbrook does not expressly disclose using a differential bridge, true low-pressure silicon die sensor. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a differential bridge, true low-pressure silicon die sensor

because the Applicant has not disclosed that this particular strain gauge provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that the strain gauge of Westbrook, or Applicant's differential bridge, true low-pressure silicon die sensor, would perform equally well to measure pressure. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Karakasoglu and Westbrook such that the sensor was a differential bridge, true low-pressure silicon die sensor, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Karakasoglu and Westbrook.

Regarding claim 10, Karakasoglu discloses all the elements of the current inventions except for using a universal serial bus (USB) interface to connect between the portable unit and another device. Westbrook teaches a system for monitoring respiration comprising a USB interface that may be used to connect a portable data acquisition unit to another device (paragraph [0078]), in order to reliably and simply transmit the data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu with a USB interface, as taught by Westbrook, in order to simply and reliably transmit the data.

8. Claims 11, 13, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Starr (US Patent 6342040).

Regarding claim 11, Karakasoglu discloses all the elements of the current invention, as described above, except for the device being powered by a battery. Starr

teaches a device for monitoring respiration using pressure sensors that may be powered by a battery (column 18, lines 12-21 and 44-46), in order to increase the portability of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu with a battery for power, as taught by Starr, in order to increase the system's portability.

Regarding claim 12, Karakasoglu discloses a portable data acquisition unit configured to collect patient information during a sleep session comprising a housing configured to be attached to a patient (element 11); a solid-state pressure sensor that is configured to measure pressure signals collected by a patient interface positioned adjacent the patient's nostrils (figure 1; sensors 71 and 71a, which are housed in element 66); an amplifier that amplifies the pressure signals and an A/D converter that converts the signals to digital signals (step 131 of figure 5; column 6, lines 15-24); a microprocessor that receives the digital signals and determines clock times associated with the digital signals (element 101; column 4, lines 24-56); an an interface that is configured to transfer the data to another device (column 10, lines 24-26). Karakasoglu does not disclose the system comprising a battery to power the unit. Starr teaches a device for monitoring respiration using pressure sensors that may be powered by a battery (column 18, lines 12-21 and 44-46), in order to increase the portability of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu with a battery for power, as taught by Starr, in order to increase the system's portability.

Regarding claim 16, Karakasoglu further discloses using the system to measure data at a rate of 6-10 kHz (column 6, line 59).

Regarding claim 17, Karakasoglu further discloses that the microprocessor is a digital signal processor (column 4, line 45) that comprises non-volatile memory (column 9, lines 50-55) including logic that controls generation of sleep session data (column 8, lines 40-55; column 10, lines 1-10).

Regarding claim 18, Karakasoglu further discloses the memory including an algorithm that is configured to analyze pressure and time data to identify sleep disordered breathing events (column 8, lines 40-55; column 10, lines 1-10).

Regarding claim 19, Karakasoglu further discloses that the microcontroller is configured to mark identified events to identify them to a user (column 10, lines 1-10).

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Starr, as applied to claims 11, 13, and 16-19 above, and further in view of Scanlon (US Patent 5853005).

Karakasoglu in view of Starr discloses all the elements of the current invention, as described above, except for part of the system being configured to mount on the patient's arm. Scanlon teaches a respiratory monitoring system wherein the system's housing may be mounted on a patient in any desired location, such as a limb (figures 7, 10, 12, since the device is attached to a strap that may be wrapped around an arm), in order to make it easier to keep the device close to the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have

made the system of Karakasoglu in view of Starr and configured it such that it could be mounted on an arm using an arm band, as taught by Scanlon, in order to make it easier to keep the device close to the patient.

10. Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Starr as applied to claims 11, 13, and 16-19 above, and further in view of Westbrook.

Regarding claim 15, the examiner notes that Westbrook does not expressly disclose using a differential bridge, true low-pressure silicon die sensor. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a differential bridge, true low-pressure silicon die sensor because the Applicant has not disclosed that this particular strain gauge provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that the strain gauge of Westbrook, or Applicant's differential bridge, true low-pressure silicon die sensor, would perform equally well to measure pressure. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Karakasoglu, Starr, and Westbrook such that the sensor was a differential bridge, true low-pressure silicon die sensor, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Karakasoglu, Starr, and Westbrook.

Regarding claim 20, Karakasoglu in view of Starr discloses all the elements of the current inventions except for using a universal serial bus (USB) interface to connect

between the portable unit and another device. Westbrook teaches a system for monitoring respiration comprising a USB interface that may be used to connect a portable data acquisition unit to another device (paragraph [0078]), in order to reliably and simply transmit the data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu in view of Starr with a USB interface, as taught by Westbrook, in order to simply and reliably transmit the data.

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Raymond (US Patent 5778882).

Karakasoglu discloses all the elements of the current invention, as disclosed above, except for the logic being configured to compress the collected data. Raymond teaches a data acquisition program stored on a computer-readable medium that is used to monitor a patient's breathing signals during sleep that is configured to compress collected data (column 8, lines 50-55), in order to reduce the amount of memory used by each sleep session. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the program of Karakasoglu with logic configured to compress the data, as taught by Raymond, in order to reduce the amount of memory used for each sleep session.

12. Claims 29, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Dunning.

Regarding claim 29, Karakasoglu discloses all the elements of the current invention, as described above, except for printing the downloaded data as a report.

Dunning teaches a method of monitoring a patient's respiration comprising printing data downloaded from a portable acquisition unit (column 8, lines 14-18; element 120), in order to create a permanent record of the data and provide hard results for further review. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of Karakasoglu and printed the downloaded data as a report, as taught by Dunning, in order to create a permanent record of the data and provide hard results for further review.

Regarding claim 30, Karakasoglu discloses all the elements of the current invention, as described above, except for presenting plots of pressure versus time. Dunning teaches a method of monitoring a patient's respiration comprising manipulating data downloaded from a portable acquisition unit to present plots of pressure versus time (column 9 line 24 to column 10 line 37), in order to completely analyze the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Karakasoglu and presented plots of pressure versus time, as taught by Dunning, in order to completely analyze the patient's condition.

Regarding claim 33, Karakasoglu discloses all the elements of the current invention, as described above, except for analyzing the data with the computer after downloading it from the portable unit. Dunning teaches a method of monitoring a patient's respiration comprising performing analysis on data downloaded to a computer

from a portable data acquisition unit (column 9 line 24 to column 10 line 37), in order to reduce the components needed in the portable unit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Karakasoglu and further analyzed the data on the computer after downloading it from the portable data acquisition unit, as taught by Dunning, in order to reduce the components needed in the portable unit.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6368287 to Hadas, which discloses a similar system and method.

US Patent 7118536 to Haberland, which discloses a similar system and method.

US Patent Application Publication 2005/0042589 to Hatlestad, which discloses a similar system and method.

US Patent 6849049 to Starr, which discloses a similar system and method.

US Patent 5797852 to Karakasoglu, which discloses a similar system and method.

US Patent 5174287 to Kallok, which discloses a similar system and method.

US Patent 5944680 to Christopherson, which discloses a similar system and method.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ket

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